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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/034,589	12/28/2001	Stephen T. Kuehn	S16.12-0128	1702

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EXAMINER

ROANE, AARON F

ART UNIT PAPER NUMBER

3739

DATE MAILED: 09/28/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/034,589

Applicant(s)

KUEHN ET AL.

Examiner

Aaron Roane

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 28 July 2005.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-21 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-21 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1-8, 10-20 are rejected under 35 U.S.C. 102(b) as being anticipated by Garrison et al. (USPN 5,972,030).

Regarding claims 1, 4, 5, 7 and 8, Garrison et al. teach all of the limitations of these claims. Garrison et al. teach an apparatus that can hold an annuloplasty ring including: a) a holder body (70) configured to hold an annuloplasty ring; b) a handle coupling (80) mounted with the holder body configured to couple to the tip of a handle, wherein handle coupling includes an opening is raised and may be used for gripping; c) a handle; and d) a release mechanism (various types of interconnection means listed in beginning on col. 18, line 60 and ending on col. 19, line 2) coupled to the handle coupling (82), a non-circular slot or opening, see col. 14-18. Regarding the “opening in the handle coupling being moveable between a lock position where the handle tip engages the opening and an

unlock position where the handle tip is released from the opening” Garrison et al. clearly disclose this claimed feature, see col. 18, line 60 through col. 19, line 2.

Regarding claims 2 and 3, Garrison et al. further disclose that the device includes a spring to bias the handle coupling into a lock position, see beginning on col. 18, line 60 and ending on col. 19, line 2. The release mechanism and spring inherently transmit a force to provide a lock or unlocked position.

Regarding claim 10, Garrison et al. further disclose the claimed invention. The surface (the surface of 80) about the opening or slot (82) is raised and provides a gripping surface to which the handle tip (26) grips and/or locks to.

Regarding claim 11, Garrison et al. further disclose many embodiments wherein the handle coupling slides into the holder body in a direction that is parallel to a plane of the holder body, see figures 12A and 12B. A plane of the holder body is so broad that there are infinite number of planes of the holder body that are parallel to the motion or slide direction shown in figures 12A and 12B.

Regarding claim 12, Garrison et al. further disclose a handle (10), see col. 12, lines 18-38 and figures 1, 3 and 4.

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Regarding claims 6 and 13, Garrison et al. further disclose a protuberance (34) on the tip (26) of the handle (10), see col. 12, lines 18-60 and col. 18 and 19 and figure 1-4.

Regarding claim 14, Garrison et al. further disclose the release mechanism being a button (44), see col. 12, lines 18-38 and figure 2.

Regarding claims 15 and 16, Garrison et al. further disclose a handle coupling comprising a clip (124) that is slidable within the holder body and provides locking and release capability, see col. 17, lines 30-58 and figure 12A.

Regarding claims 17 and 20, Garrison et al. disclose a handle (10) comprising an elongate shaft (20), a gripping portion (28) that includes ribs (the ribbed or grooved button 30 section with the handle 28) and a tip (26) coupled to the other end of the elongate shaft (with respect to the gripping portion), see col. 12 and figures 1-4. It should be noted that the tip disclosed by Garrison et al. has many walls (flat surfaces), see figure 2.

Regarding claim 18, Garrison et al. further disclose flat portions various flat sections on (28) on the handle, see figure 1.

Regarding claim 19, Garrison et al. further disclose a tip with walls (flat sides in 36 and 39 are located) that are aligned with some of the flat portions on the handle (the side flat surfaces 90° away from the flat portion with the button therein), see figures 1 and 2.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 9 and 21 are rejected under 35 U.S.C. 103(a) as being unpatentable over Garrison et al. (USPN 5972030) in view of Rhee et al. (USPN 6019739).

Regarding claims 9 and 21, Garrison et al. teach all of the limitations of these claims as described above except for the opening and walls of the tip of the handle being tapered.

Additionally Garrison et al. list a large number of equivalent locking/release or interconnection means, see beginning on col. 18, line 60 and ending on col. 19, line 2.

Rhee et al. teach a similar device including a body, handle coupling, and handle where the body has a tapered opening for receiving the tapered tip of a handle (figure 1).

Therefore, at the time of invention it would have been obvious to one of ordinary skill in the art to modify the device of Garrison et al., as taught by Rhee et al., to include a handle coupling mechanism having a tapered opening and tip with tapered walls as part of a suitable means for coupling the handle to the holder body.

Response to Arguments

Applicant's arguments filed 7/28/2005 have been fully considered but they are not persuasive.

Applicant asserts (see page 5, line 9) Garrison et al. do not "set forth the structural limitations in claim 1 of a handle coupling having an opening, the handle coupling mounted with the holder body to couple the holder body to a handle having a tip, the opening in the handle coupling being moveable between a lock position where the handle tip engages the opening and a unlock position where the handle tip is released from the opening." Essentially, the amendment that Applicant made simply added "the opening in the handle coupling being moveable between a lock position where the handle tip engages the opening and a unlock position where the handle tip is released from the opening." The examiner provided the specific passage in Garrison et al. detailing this claimed feature. Additionally, Garrison et al. meet this specific recitation in two ways: 1) Functional definition: the opening disclosed by Garrison et al. is moveable between a fixed engagement with the handle tip (this is the lock position) and free disengagement with respect to the handle tip (this is the unlock position) and 2) Actual structure that meeting the function of lock/unlock between the opening and handle tip (e.g., luer locks, snap fit, etc.). Therefore, as set forth by the claim language, the Garrison et al. patent meets the presently claimed subject matter of claim 1.

Next Applicant refutes the rejections made under 35 U.S.C. §103. The examiner wishes to thank Applicant for highlighting and reviewing the criteria necessary for making rejection under obviousness. Applicant states the first criterion is that there must be some suggestion or

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motivation, either in the references themselves or in the knowledge generally available to one of ordinary skill in the art, to modify the reference. Garrison et al. disclose a wide variety of alternate ways for providing securement between the handle tip and opening and therefore it would have been obvious to one of ordinary skill in the art to use as an alternate securement modality the securement structure of the handle tip and opening disclosed in the Rhee et al. patent.

Secondly, there must be a reasonable expectation of success. This criterion is clearly not an issue since all of the individual opening/tip securement methods are known in the art to work.

Third and finally, Applicant points out the combination of prior art must teach or suggest all the claimed limitations. Since the examiner has shown how Garrison et al. meet the presently amended claim 1, this criterion is also met.

This action is FINAL.

Conclusion

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO**

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MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Aaron Roane whose telephone number is (571) 272-4771. The examiner can normally be reached on Monday-Thursday 7AM-6PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Linda Dvorak can be reached on (571) 272-4764. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

A.R. *A.R.*
September 21, 2005

Roy D. Gibson
ROY D. GIBSON
PRIMARY EXAMINER